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| MODULE SPECIFICATION TEMPLATE |

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| MODULE DETAILS | | | | | | | | | | | | | | | | | | | | |
| **Module title** | Clinical Trials Management | | | | | | | | | | | | | | | | | | | |
| **Module code** | MDM112 | | | | | | | | | | | | | | | | | | | |
| **Credit value** | 20 credits | | | | | | | | | | | | | | | | | | | |
| **Level**  Mark the box to the right of the appropriate level with an ‘X’ | Level 4 |  | | Level 5 | | |  | Level 6 | | | |  | | Level 7 | | | X | Level 8 |  | |
| Level 0 (for modules at foundation level) | | | | | | | | | | |  | |  | | | | | | |
| ***Entry criteria for registration on this module*** | | | | | | | | | | | | | | | | | | | | |
| **Pre-requisites**  Specify in terms of module codes or equivalent | Completion of the NIHR Good Clinical Practice (GCP) Course. Students may complete the GCP Training during the module. (Students must submit a copy of their GCP certificate with the module assignment.) | | | | | | | | | | | | | | | | | | | |
| **Co-requisite modules**  Specify in terms of module codes or equivalent | N/A | | | | | | | | | | | | | | | | | | | |
| ***Module delivery*** | | | | | | | | | | | | | | | | | | | | |
| **Mode of delivery** | Taught | | X | | Distance | | | |  | | Placement | | | | |  | Online | | |  |
|  | Other | |  | | | | | | | | | | | | | | | | | |
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| **Pattern of delivery** | Weekly | |  | | Block | | | | X | | Other | | | | |  | | | | |
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| **When module is delivered** | Semester 1 | | | | X | Semester 2 | | | | | | | X | | Throughout year | | | | |  |
| Other | |  | | | | | | | | | | | | | | | | | |
| **Brief description of module content and/ or aims**  Overview (max 80 words) | This is a pragmatic multidisciplinary and multi-centred module that is specifically designed for all health professionals involved in clinical trials and in the management of research projects. Participants will be able to apply their learning immediately to their work. | | | | | | | | | | | | | | | | | | | |
| **Module team/ author/ coordinator(s)** | Muzaffar Malik, Senior Lecturer  John Anderson, Principal Lecturer (Acting Module Leader) | | | | | | | | | | | | | | | | | | | |
| **School** | BSMS | | | | | | | | | | | | | | | | | | | |
| **Site/ campus where delivered** | Falmer and possibly other sites in KSS | | | | | | | | | | | | | | | | | | | |
| ***Course(s) for which module is appropriate and status on that course*** | | | | | | | | | | | | | | | | | | | | |
| **Course** | | | | | | | | | | **Status (mandatory/ compulsory/ optional)** | | | | | | | | | | |
| MRes (Medical Research) | | | | | | | | | | Optional | | | | | | | | | | |
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| Any other course for which this may be suitable.  It is also available as a stand-alone module for NHS staff and other interested people. | | | | | | | | | | | | | | | | | | | | |

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| MODULE AIMS, ASSESSMENT AND SUPPORT | | |
| **Aims** | The aim of the module is to enable health practitioners and specialist researchers to develop their knowledge and ability to participate in and conduct clinical trials research. This aims to cater for professionals from a wide range of backgrounds. The emphasis is on Multidisciplinary working for all staff in clinical trials. It is intended that this education and training should be delivered at multiple sites to enhance its accessibility. It is intended to provide training to equip participants with knowledge to be future CIs/PIs of clinical trials. | |
| **Learning outcomes** | On successful completion of the module participants will be able to:   1. Have a comprehensive understanding of the design and management of clinical trials. 2. Implement principles and strategies of trial management 3. Understand the relationship between researchers and industry in clinical trials 4. Have an advanced level of understanding of Good Clinical Practice (GCP) Guidelines, and research ethics and governance in clinical settings. 5. Be able to conform to statutory requirements when conducting clinical trials in medicine and surgery. | |
| **Content** | * Understanding clinical research in healthcare and the relationship between researchers and industry * Recruitment and Management of research staff and study participants * Legal and regulatory processes and the role of the Medicines and Healthcare products Regulatory Agency (MHRA) * Financial management issues of clinical research with funding agencies and industry * Promoting and marketing in clinical research * Research Ethics and Governance and Good Clinical Practice Guidelines * Legal aspects of Clinical Trials * Obtaining Informed Consent for Clinical Trials * Intellectual property and the Dissemination of trial results * Data management and security | |
| **Learning support** | Core reading:  *Oxford Handbook of Clinical and Healthcare Research*. Oxford University Press; 1 edition (May 3, 2016)  *Oxford Handbook of Medical Statistics*. OUP Oxford; 1 edition (4 Nov. 2010)  Wang, D and Bakhai, A. *Clinical Trials: A Practical Guide to Design, Analysis, and Reporting*. Remedica; 2005  Glick, HA et. al. *Economic Evaluation in Clinical Trials*. Oxford University Press; 2 edition (1 Dec. 2014)  GCP training:  <http://www.nihr.ac.uk/our-faculty/clinical-research-staff/learning-and-development/national-directory/good-clinical-pratice/>  Important Online Resources:  WHO International Clinical Trials (<http://apps.who.int/trialsearch/>)  UK Clinical Trials Gateway (<https://www.ukctg.nihr.ac.uk/>)  Health Research Authority UK (<http://www.hra.nhs.uk/>)  National Institute for Health Research (<http://www.nihr.ac.uk/>)  Trial documentation (<http://www.ct-toolkit.ac.uk/routemap/trial-documentation>)  Additional reading:  George, TC. *Medical Writing for Essential Clinical Trial Documents: A training manual to learn & create clinical trial documents*. CreateSpace Independent Publishing Platform; 1 edition (25 Mar. 2015)  Brody, T. *Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines*. Academic Press; 2 edition (14 Mar. 2016)  Cook, TD and DeMets, DL. Introduction to Statistical Methods for Clinical Trials. Chapman and Hall/CRC; 1 edition (19 Nov. 2007). | |
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| ***Teaching and learning activities*** | | |
| **Details of teaching and learning activities** | Lectures, Discussions, Workshops, Visits, Videos, and Online education (blended learning) using examples from published research and discussing interpretations. Interactive problem-solving and case-studies will be included as a means of engaging participants in the issues. Real-life examples will be included wherever possible. | |
| **Allocation of study hours (indicative)**  Where 10 credits = 100 learning hours | | **Study hours** |
| **SCHEDULED** | Classroom work | 35 |
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| **GUIDED INDEPENDENT STUDY** |  | 165 |
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| **PLACEMENT** | N/A | - |
| **TOTAL STUDY HOURS** | | **200** |
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| ***Assessment tasks*** | | |
| **Details of assessment on this module** | 4,500 word critical report on the design and conduct of a Clinical Trial or a grant application or a study protocol (Students must submit a copy their GCP certificate with the module assignment.)" | |
| **Types of assessment task[[1]](#footnote-1)**  Indicative list of summative assessment tasks which lead to the award of credit or which are required for progression. | | **% weighting**  (or indicate if component is pass/fail) |
| **WRITTEN** | N/A | 0 |
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| **COURSEWORK** | 4,500 word critical report on the design and conduct of a Clinical Trial. | 100 |
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| **PRACTICAL** | N/A | 0 |
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| EXAMINATION INFORMATION | | | | |
| **Area examination board** | PG Exam Board, BSMS | | | |
| Refer to University for guidance in completing the following sections | | | | |
| ***External examiners*** | | | | |
| **Name** | | **Position and institution** | **Date appointed** | **Date tenure ends** |
| Dr Claire Parkin | | University of Kent, Centre for Professional Practice | September 2019 | September 2023 |

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| QUALITY ASSURANCE | | | | | |
| **Date of first approval**  Only complete where this is not the first version | April 2014 | | | | |
| **Date of last revision**  Only complete where this is not the first version | September 2014 | | | | |
| **Date of approval for this version** | June 2016 | | | | |
| **Version number** | 2 | | | | |
| **Modules replaced**  Specify codes of modules for which this is a replacement | N/A | | | | |
| **Available as free-standing module?** | | **Yes** | **X** |  |  |

1. Set exercises, which assess the application of knowledge or analytical, problem-solving or evaluative skills, are included under the type of assessment most appropriate to the particular task. [↑](#footnote-ref-1)